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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. ART-00104.P.1.2 4793 10/725,160 12/01/2003 Lei Wu EXAMINER 11/03/2005 24232 YANG, NELSON C DAVID R PRESTON & ASSOCIATES APC 12625 HIGH BLUFF DRIVE PAPER NUMBER ART UNIT SUITE 205 SAN DIEGO, CA 92130 1641

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application	Application No. Applicant(s)		-	
		10/725,16	60	WU ET AL.		
		Examiner		Art Unit		
		Nelson Ya	ng	1641		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on <u>01 December 2003</u> .					
-	•	is action is non-final.				
· —		ation is in condition for allowance except for formal matters, prosecution as to the merits is				
-,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>49-56</u> is/are pending in the application.						
•	4a) Of the above claim(s) is/are withdrawn from consideration.					
	5) Claim(s) is/are allowed.					
,	5)⊠ Claim(s) <u>49-56</u> is/are rejected.					
-	8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 09/399,299. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/15/04 4) Interview Summary (PTO-413) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) Other:						

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DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claims 1-48 is acknowledged and has been entered.

2. Claims 49-56 are currently pending.

Specification

3. The disclosure is objected to because of the following informalities: throughout the disclosure, applicant refers to magentophoresis, magnetophoresis and magentophoretic. It is unclear if these are all the same, or if they are referring to different concepts. Further clarification would be greatly appreciated.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 50, 51, 54, 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 6. Claim 50 recites that the moiety is optionally linked to the magnetic particle. It is unclear whether this is a required limitation or not, and as a result, whether claim 51 is a required limitation as well. Currently it is assumed that since the linkage is optional, it is not required.
- 7. Claim 54 recites a particle switch. It is unclear if what a particle switch is whether it refers to the specific configuration of electromagnetic units as depicted in fig. 39A or if it refers to a function or capability of the electromagnetic units. Further clarification would be greatly appreciated.

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8. Claim 55 recites that the core optionally comprises at least one terminal structure. It is unclear whether this is a required limitation or not.

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Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 10. Claims 49-52, 55, 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cabelli [US 5,814,376].

With respect to claim 49, Cabelli teaches the use of a magnetic device comprised of an array of magnetic pole-pieces of high relative permeability alternating with appropriately oriented magnetic structural elements to provide a focused magnetic field that will attract the magnetic components used in an assay to the surface of a receptacle, such as an electroconductive cell (column 2, lines 27-33). Specifically, Cabelli teaches a magnetic field applied to a sensor for one minute to draw magnetic complexes to the electrode assembly surface after incubation of a solution containing a sample, reporter conjugate, and magnetic complexes in the center cell of the sensor (column 19, lines 35-60), wherein the magnetic complexes comprise magnetic particles (column 5, lines 63-65).

- 11. With respect to claim 50, Cabelli teaches magnetic particles with a surface modified to provide chemical groups to which antibodies can be attached (column 5, lines 63-65).
- 12. With respect to claim 51, Cabelli teaches that the antibodies can be attached through covalent bonds (column 5, lines 65-67).

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13. With respect to claim 52, Cabelli teaches that moieties such as antibodies can be attached through covalent bonds (column 5, lines 65-67).

- 14. With respect to claim 55, the magnetic field device comprises a material of silicon core iron (column 8, lines 22-30).
- With respect to claim 56, the device taught by Cabelli contains circular dips (31) (fig.2).

 Claim Rejections 35 USC § 103
- 16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chalmers et al [Chalmers et al, An instrument to determine the magnetophoretic mobility of labeled, biological cells and paramagnetic particles, 1999, J Magnetism and Magnetic Materials, 194, p.231-241].

Cabelli teaches the use of a magnetic device comprised of an array of magnetic polepieces of high relative permeability alternating with appropriately oriented magnetic structural
elements to provide a focused magnetic field that will attract the magnetic components used in
an assay to the surface of a receptacle, such as an electroconductive cell (column 2, lines 27-33).

Specifically, Cabelli teaches a magnetic field applied to a sensor for one minute to draw
magnetic complexes to the electrode assembly surface after incubation of a solution containing a
sample, reporter conjugate, and magnetic complexes in the center cell of the sensor (column 19,
lines 35-60), wherein the magnetic complexes comprise magnetic particles (column 5, lines 6365). Cabelli fails to teach that the magnetic device comprises a magnetophoretic device.

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Chalmers et al, however, teach the use of a magnetophoretic device, and further teach

that it allows for separating particles or biological cells that have paramagnetic characteristics,

allowing for highly specific biological cell separations, drug deliveries, radionuclide therapy,

contrast agents in MR imaging, and the separation of organelles, mRNA, genomic DNA, and

proteins to be accomplished (p. 231, cols.1-2).

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The

examiner can normally be reached on 8:30-5:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang Patent Examiner Art Unit 1641

10/28/01